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EXAMINER  
EINSMANN, J

ART UNIT	PAPER NUMBER
1655	9

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

## Office Action Summary

Application No.

09/538,864

Applicant(s)

CHO ET AL.

Examiner

Juliet C. Einsmann

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-111 is/are pending in the application.
- 4a) Of the above claim(s) 103-107 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-102 and 108-111 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

### Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 8.
- 18) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_.
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### *Election/Restrictions*

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-102 and 108-111, drawn to transgenic plants expressing thioredoxin, method of making said plants, and feed tufts comprising said plants, classified, for example, in class 800, subclass 995.
  - II. Claim 103, drawn to methods for alleviating mal-absorption or an allergy, classified in class 424, subclass 539.
  - III. Claims 104-105, drawn to methods for producing alcohol, classified in class 424, subclass 11.
  - IV. Claims 106-107, drawn to methods for purifying thioredoxin, classified in class 530, subclass 412.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions I and II, I and III, and I and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the plants of invention I can be used in a variety of methods for a variety of purposes, including the production of the transgenic protein and as a feed product.
3. Inventions II and III, II and IV, and III and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different

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modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01).

In the instant case the different inventions are methods with different goals, method steps and using different reagents.

4. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as demonstrated by their different classification and recognized divergent subject matter and because inventions I-IV require different searches that are not coextensive, examination of these claims would pose a serious burden on the examiner and therefore restriction for examination purposes as indicated is proper.

5. During a telephone conversation with Peter Dehlinger on 4/2/01 a provisional election was made without traverse to prosecute the invention of group I, claims 1-102 and 108-111. Affirmation of this election must be made by applicant in replying to this Office action. Claims 103-107 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

#### *Specification*

7. The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01. See, for example, page 14.

*Claim Objections*

8. Claims 52 and 59 are objected to because of the following informalities: These claims have extra periods either within the claim or at the end of the claim. MPEP 601.01(m) states, "Each claim begins with a capital letter and ends with a period. Periods may not be used elsewhere in the claims except for abbreviations." Appropriate correction is required.

*Claim Rejections - 35 USC § 112*

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claims 6, 12, 13, 14, 28-31, 55, 56, and 57 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 6 is indefinite because it depends from itself.

Claims 12, 13, 14, 28-31, 55, 56, 57 are indefinite over the recitation of the phrase "increased SH:SS ratio" because the claims do not make clear the meaning of "SH:SS ratio."

Claim 63 is indefinite because the language is not clear. It is not clear if the thioredoxin protein comprises "an earlier onset and/or an increased expression of a gibberellic inducible enzyme" or if the transgenic plant has this feature. Clarification of the language is requested.

11. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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12. Claims 1-30, 44-62, 70-73, 86-102, and 108-111 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

These claims are all broadly drawn to transgenic plants, seeds and feed tuffs which are defined by specific phenotypic characteristics. In each case, the phenotypic characteristic may be caused by many different transgenes or genetic interactions with transgenes, therefore, the scope of these claims is very broad. These claims do not designate what transgene is present in the plants being claimed. However, from the specification, it is clear that applicant only has possession of transgenic plants expressing wheat thioredoxin h. Furthermore, it is clear that with regard to increased digestibility and decreased allergenicity, applicant is only in possession of wheat plants over expressing wheat thioredoxin h and Aabidopsis NTR. Applicant has not demonstrated possession of any flour, dough, bread, pasta, cookies, cake, thickeners, beer or malted beverages made from the instant plants, let alone a dough with an increased volume of at least 3%.

It is noted that in Fiers v. Sugano (25 USPQ2d, 1601), the Fed. Cir. concluded that

"...if inventor is unable to envision detailed chemical structure of DNA sequence coding for specific protein, as well as method of obtaining it, then conception is not achieved until reduction to practice has occurred, that is, until after gene has been isolated...conception of any chemical substance, requires definition of that substance other than by its functional utility."

Also, in Vas-Cath Inc. v. Mahurkar (19 USPQ2d 1111, CAFC 1991), it was concluded that:

"...applicant must also convey, with reasonable clarity to those skilled in art, that applicant, as of filing date sought, was in possession of invention, with invention being, for purposes of "written description" inquiry, whatever is presently claimed."

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In the application at the time of filing, there is no record or description which would demonstrate conception or written description of any plant resistance gene which has amino acids modified by addition, insertion, deletion, substitution or inversion with the disclosed SEQ ID Nos but retaining correlative function in the claimed product.

***Claim Rejections - 35 USC § 102***

13. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

14. Claims 1, 2, 3, 4, 8, 11, 12, 13, 28, 30, 31, 32, 33, 41, 44-47, 51, 52, 55-56, 74, 76, 77, 84 and 95-101 are rejected under 35 U.S.C. 102(b) as being anticipated by Shi *et al.* (Plant Molecular Biology, 32:653-662, 1996).

Shi *et al.* teach a transgenic plant wherein at least part of said plant has an increased specific activity of thioredoxin compared to the same part of a non-transgenic plant of the same species (p. 654 and 657). Shi *et al.* teach eight day old plants and mature plants with pods, and further teach analysis of transgenic seeds (p. 658, Col. 2). Shi *et al.* teach that the transgenic transcripts were detected in all tissues examined (p. 658). Further, Shi *et al.* teach a method for making a transgenic plant which comprises expressing in said plant a recombinant nucleic acid molecule encoding a thioredoxin polypeptide operably linked to a transcription regulatory element active in said plant (p. 654-655). When transformed with the construct pRTF51, the transgenic plant expressed the thioredoxin only in the soluble fraction.

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Therefore, the teachings of Shi *et al.* provide a transgenic plant, seeds, and methods of making a transgenic plant which has an increased specific activity of thioredoxin in comparison to the same part of a non-transgenic plant of the same species, as the transgenic tobacco taught by Shi *et al.* certainly has a higher specific activity of soybean thioredoxin than non-transgenic tobacco.

With regard to claims 2-4, 11-13, 45-47, 52, 55, and 56, although Shi *et al.* are silent with regard to the increase in the thioredoxin specific activity, transformation constructs comprised the 35S cauliflower mosaic virus promoter, and this promoter is widely known to drive high levels of constitutive expression in transgenic plants. Therefore, these levels of specific activity of thioredoxin in the transgenic plants are considered inherent properties of the plants taught by Shi *et al.* Furthermore, with regard to claims 12 and 13, the over-expression of exogenous thioredoxin in the transgenic plants will inherently change the redox status of the plants, since thioredoxin is a known reductase.

This rejection applies to claims 41 and 84 when "signal peptide" is broadly interpreted to include any peptide in the expression construct that results in a signal. The expression constructs taught by Shi *et al.* comprise a FLAG epitope, which is considered a signal as broadly interpreted.

15. Claims 17-18 are rejected under 35 U.S.C. 102(b) as being anticipated by Sewalt *et al.* (J. Agr. Food Chem, 1997, 45, 1977-1983).

Sewalt *et al.* teach plants with increased enzyme digestibility of cell walls from stem internodes (ABSTRACT, and throughout).

16. Claims 17-20, 23-24, 28-30, 60 and 61 are rejected under 35 U.S.C. 102(b) as being anticipated by van Ooijen *et al.* (US 5543576).



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Van Ooijen *et al.* teach transgenic plants and seeds expressing phytase. The phytase in the seeds increases the digestibility of the phytase the seeds by liberating phosphate from the phytates (Example 11). Van Ooijen *et al.* exemplifies the expression of phytase in tobacco and rapeseed (Example 8 and 9). Furthermore, Van Ooijen *et al.* teach seed-specific expression of the phytase, and the seeds that result therefrom (Examples 8 and 9).

Furthermore, Van Ooijen *et al.* teach transgenic plants expressing  $\alpha$ -amylase (Example 15). This plant is considered to have an increased of  $\alpha$ -amylase in comparison to the same part of a non-transgenic plant of the same species because it is expressing an exogenous  $\alpha$ -amylase.

17. Claims 70-72 are rejected under 35 U.S.C. 102(b) as being anticipated by Vincentez *et al.* (US 5569833).

Vincentez *et al.* teach transgenic seeds that have increased germination rates in comparison to non-transgenic seeds of the same species (Col. 7, lines 35-55). The progeny of the transformed plant germinated nine days before that of the wild-type (Col. 7, lines 53-54).

### ***Claim Rejections - 35 USC § 103***

18. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

19. Claims 7, 15, 16, 17, 18, 20-26, 50, 58-59, 60-61, and 63-72 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Shi *et al.*

Shi *et al.* teach a transgenic plant wherein at least part of said plant has an increased specific activity of thioredoxin compared to the same part of a non-transgenic plant of the same species (p. 654 and 657). Shi *et al.* teach eight day old plants and mature plants with pods, and further teach analysis of transgenic seeds (p. 658, Col. 2). Shi *et al.* teach that the transgenic transcripts were detected in all tissues examined (p. 658). Further, Shi *et al.* teach a method for making a transgenic plant which comprises expressing in said plant a recombinant nucleic acid molecule encoding a thioredoxin polypeptide operably linked to a transcription regulatory element active in said plant (p. 654-655). When transformed with the construct pRTF51, the transgenic plant expressed the thioredoxin only in the soluble fraction.

Therefore, the teachings of Shi *et al.* provide a transgenic plant, seeds, and methods of making a transgenic plant which has an increased specific activity of thioredoxin in comparison to the same part of a non-transgenic plant of the same species, as the transgenic tobacco taught by Shi *et al.* certainly has a higher specific activity of soybean thioredoxin than non-transgenic tobacco.

Each of the claims included in this rejection include the recitation of a characteristic of the transgenic plants. Shi *et al.* are silent as to the presence of these characteristics. However, the only structural limitation imposed by the claim language is that a thioredoxin gene be expressed as a transgene in a plant. Therefore, these phenotypes are considered inherent properties of the transgenic plants provided by Shi *et al.* (See MPEP 2112). The examiner reasons that these characteristics exist in the transgenic plants taught by Shi *et al.* because the recited enzyme is being expressed in the plants, and the specification admits that the expression of exogenous thioredoxin in transgenic plants results in these characteristics. It is noted that

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"Once a reference teaching product appearing to be substantially identical is made the basis of a rejection and the examiner presents evidence or reasoning tending to show inherency, the burden shifts to the applicant to show an unobvious difference (MPEP 2112)." Furthermore, with regard to claims 7 and 50, Shi *et al.* are silent with regard to the specific activity of the thioredoxin which they express in the transgenic plants. However, it is considered that this thioredoxin inherently has a specific activity of at least 1-2 absorbance units at 534 nm/30min/mg protein.

20. Claims 5, 6, 9, 10, 39, 40, 48, 49, 53, 54, 82, and 83 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shi *et al.* in view of Rivera-Madrid *et al.* (PNAS USA 92:5620-5624, 1995).

Shi *et al.* teach a transgenic plant wherein at least part of said plant has an increased specific activity of thioredoxin compared to the same part of a non-transgenic plant of the same species (p. 654 and 657). Shi *et al.* teach eight day old plants and mature plants with pods, and further teach analysis of transgenic seeds (p. 658, Col. 2). Shi *et al.* teach that the transgenic transcripts were detected in all tissues examined (p. 658). Further, Shi *et al.* teach a method for making a transgenic plant which comprises expressing in said plant a recombinant nucleic acid molecule encoding a thioredoxin polypeptide operably linked to a transcription regulatory element active in said plant (p. 654-655). When transformed with the construct pRTF51, the transgenic plant expressed the thioredoxin only in the soluble fraction.

Therefore, the teachings of Shi *et al.* provide a transgenic plant, seeds, and methods of making a transgenic plant which has an increased specific activity of thioredoxin in comparison to the same part of a non-transgenic plant of the same species, as the transgenic tobacco taught

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by Shi *et al.* certainly has a higher specific activity of soybean thioredoxin than non-transgenic tobacco.

Shi *et al.* do not teach methods in which the thioredoxin expressed is a thioredoxin h.

Rivera-Madrid *et al.* teach the cDNAs encoding five thioredoxin h polypeptides from Arabidopsis (p. 5621). Further, Rivera-Madrid *et al.* teach methods in which the polypeptide was over expressed in E. coli (p. 5621). It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to have made transgenic plants expressing these thioredoxin h molecules. The ordinary practitioner would have been motivated to transform transgenic plants with these molecules in order to further study the biological function of the thioredoxin h polypeptides plants, or as an alternative method for producing thioredoxin h polypeptides for study. Shi *et al.* teach methods for expression of the gene in plants, and provide methods for the use of FLAG to purify the produced enzyme. The ordinary practitioner would have been motivated by the success of Shi *et al.*'s expression of thioredoxin to extend this method to the thioredoxin molecules taught by Rivera-Madrid *et al.*

21. Claims 14, 19, 27, 29, 34, 35, 38, 41, 42, 57, 62, 73, 74, 75, 78, 85, 93-94, 87-90, 102, and 108-111 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shi *et al.* in view of van Ooijen *et al.*

Shi *et al.* teach a transgenic plant wherein at least part of said plant has an increased specific activity of thioredoxin compared to the same part of a non-transgenic plant of the same species (p. 654 and 657). Shi *et al.* teach eight day old plants and mature plants with pods, and further teach analysis of transgenic seeds (p. 658, Col. 2). Shi *et al.* teach that the transgenic

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transcripts were detected in all tissues examined (p. 658). Further, Shi *et al.* teach a method for making a transgenic plant which comprises expressing in said plant a recombinant nucleic acid molecule encoding a thioredoxin polypeptide operably linked to a transcription regulatory element active in said plant (p. 654-655). When transformed with the construct pRTF51, the transgenic plant expressed the thioredoxin only in the soluble fraction.

Therefore, the teachings of Shi *et al.* provide a transgenic plant, seeds, and methods of making a transgenic plant which has an increased specific activity of thioredoxin in comparison to the same part of a non-transgenic plant of the same species, as the transgenic tobacco taught by Shi *et al.* certainly has a higher specific activity of soybean thioredoxin than non-transgenic tobacco.

Some of the claims included in this rejection include the recitation of a characteristic of the transgenic plants. Shi *et al.* are silent as to the presence of these characteristics. However, the only structural limitation imposed by the claim language is that a thioredoxin gene be expressed as a transgene in a plant. Therefore, these phenotypes are considered inherent properties of the transgenic plants provided by Shi *et al.* (See MPEP 2112). The examiner reasons that these characteristics exist in the transgenic plants taught by Shi *et al.* because the recited enzyme is being expressed in the plants, and the specification admits that the expression of exogenous thioredoxin in transgenic plants results in these characteristics. It is noted that "Once a reference teaching product appearing to be substantially identical is made the basis of a rejection and the examiner presents evidence or reasoning tending to show inherency, the burden shifts to the applicant to show an unobvious difference (MPEP 2112)."

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Shi *et al.* do not teach the transformation of plants other than tobacco. Nor do Shi *et al.* teach methods in which the transgenic seeds produced are used in food products. Further, Shi *et al.* do not teach methods in which the seeds produced by the transgenic plants are germinated.

However, at the time the invention was made, each of these products was routine in the art. For example, Van Ooijen *et al.* teach transgenic plants useful for the production of enzymes in the seeds. Van Ooijen *et al.* teach that this method is especially useful because the enzymes can be used directly in the seeds without further purification (Col. 3, lines 37-41). Van Ooijen *et al.* teach the transformation of many different genera of plants using methodology similar to that used Shi *et al.* Van Ooijen *et al.* teach that a variety of plants, including grains, are useful in such methods, such as barley, rice and maize (Col. 6, lines 13-14). Van Ooijen *et al.* also teach that vectors comprising a constitutive promoter such as a 35S cauliflower mosaic virus promoter will result in the accumulation of the expressed protein in the plant (Col. 1, lines 60-65). Further, they teach that seed specific promoters can also be used (Col. 7, lines 55-60), and the use of signal peptides to direct the expression of the transgene product (Col. 24, lines 10-15). Van Ooijen exemplify the use of the seeds from transgenic plants expressing industrial enzymes, including tobacco seeds, in animal feed (Col. 18). Van Ooijen *et al.* teach methods in which the transgenic seeds are germinated to produce progeny (Col. 16, lines 30-35).

Thioredoxins were widely known at the time the invention was made to be enzymes with many industrial uses, including in the flour making industry, as is admitted by the instant specification. Therefore, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to have modified the products taught by Shi *et al.* using any of the routine modifications taught by Van Ooijen *et al.* At the time the invention was made,

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the selection of one of any number of plant species to be transformed for the expression of industrial enzymes would have been routine. Furthermore, the use of a seed specific promoter and a signal sequence would have been motivated by the teachings of Van Ooijen *et al.* for the production of industrial enzymes in plants. The use of the transgenic seeds as feed products would have been further obvious, since this is one of the major reasons Van Ooijen *et al.* cite for the utility of their products. They teach that the seeds "can be used in various industrial processes or in food and feed stuffs as catalysts for digestive reactions, without the need for first extracting and/or isolating the enzymes (Col. 3, lines 37-41)." The ordinary practitioner would have been motivated by the successful expression of thioredoxins in plants by Shi *et al.* and by the teachings concerning the production of transgenic plants for the production of industrial enzymes as taught by Van Ooijen *et al.* to produce the plants of the instant invention. In the absence of a secondary consideration, such as an unexpected result, the instantly broadly claimed invention is free of the prior art.

22. Claims 36-37, 43, and 79-81 rejected under 35 U.S.C. 103(a) as being unpatentable over Shi *et al.* in view of van Ooijen *et al.* as applied to claims 14, 19, 27, 29, 34, 35, 38, 41, 42, 57, 62, 73, 74, 75, 78, 85, 93-94, 87-90, 102, and 108-111 above, and further in view of Cho *et al.* (In vitro Cellular and Developmental biology 34(3) part 2 (March 1998) p. 48A).

The teachings of Shi *et al.* in view of van Ooijen *et al.* are applied to this rejection as discussed above. Neither Shi *et al.* nor van Ooijen *et al.* teach the use of a barley B1 Hordein promoter or signal peptide. However, van Ooijen *et al.* do specifically teach that the sequences taught in their constructs may be replaced "by those from similar seed-specific genes to achieve the same goal as is the objective of this invention (Col. 15, lines 11-14)."

Cho *et al.* teach the barley B<sub>1</sub>-hordein regulatory regions and signals that direct sub-cellular localization of proteins in the endosperm. They teach that stronger activity was detected when the transformed endosperm tissue contained the signal sequence that without the signal sequence. Further they teach that the gene driven by the B<sub>1</sub>-hordein regulatory elements was stably inherited and expressed in T<sub>2</sub> progeny.

Therefore, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to have used the regulatory sequences and signal sequence taught by Cho *et al.* to produce transgenic plants as taught by Shi *et al.* in view of van Ooijen *et al.* The ordinary practitioner would have been motivated by the teachings of Cho *et al.* that the barley B<sub>1</sub>-hordein regulatory element coupled with the signal sequence drive endosperm specific expression and by the teachings of van Ooijen that other seed specific promoters can be used in to produce transgenic plants according to their invention.

### ***Conclusion***

23. It is noted that the specification provides evidence of unexpected results with regard to barley plants expressing wheat thioredoxin h and wheat plants transformed with both wheat thioredoxin h and Arabidopsis NTR.

With regard to barley plants expressing wheat thioredoxin h, the specification demonstrates that seeds produced from these plants have increased activity of  $\alpha$ -amylase and pullulanase. Further, it was demonstrated that seeds from these plants germinate earlier than seeds from transgenic plants lacking the transgene.



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With regard to wheat plants over-expressing wheat thioredoxin h and Arabidopsis NTR, the specification provides unexpected results with regard to increased digestibility and reduced allergenicity in these plants.

Claims which are drawn commensurate in scope with these unexpected results would not be considered obvious over the prior art. For example, a transgenic barley plant wherein at least part of said plant comprises a recombinant nucleic acid comprising a promoter active in said part operably linked to a nucleic acid molecule encoding a wheat thioredoxin h polypeptide, would be allowable.

24. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Juliet C. Einsmann whose telephone number is (703) 306-5824. The examiner can normally be reached on Monday through Thursday, 7:00 AM to 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones can be reached on (703) 308-1152. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 and (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

  
Juliet C. Einsmann  
Examiner  
Art Unit 1655

April 23, 2001

  
W. Gary Jones  
Supervisory Patent Examiner  
Technology Center 1600

4/23/01